ETHICAL IMPLICATIONS OF OBTAINING VOLUNTARY INFORMED CONSENT ON KOMBEWA HEALTH AND DEMOGRAPHIC SURVEILLANCE SYSTEM IN WESTERN KENYA

By

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DECLARATION

Declaration by the Candidate

This thesis is my original work and has not been presented for the award of a degree in any other university. No part of this thesis may be reproduced without the prior permission of the author and Moi University.

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Declaration by Supervisors

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DEDICATION

This thesis is dedicated to the memory of my loving husband, Professor Omar Badiru Egesah, and my family for their unending support and understanding throughout this degree study, as well as for always being there to offer moral support.

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LIST OF ACRONYMS / ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
CIOMS	Council for International Organization of Medical Sciences
DO	District Officer
DSA	Demographic Surveillance Area
EA	Enumeration Area
GCP	Good Clinical Practices
GPS	Global Positioning System
HDSS	Health and Demographic Surveillance System
HH	House Hold
HHH	House Hold Head
HIV	Human Immuno Deficiency Virus
IC	Informed Consent
IHRE	International Health Research Ethics
INDEPTH	International Network for the Demographic Evaluation of Populations and Their Health
IRB	Institutional Review Board
IREC	Institutional Research Ethics Committee
KEMRI	Kenya Medical Research Institute
KHDSS	Kombewa Health and Demographic Surveillance System (KHDSS) was implemented
KII	Key Informant Interview
NACOSTI	National Council for Science, Technology and Innovation
PI	Principal Investigator
RAs	Research Assistants

RTS	Scientific Name Given to the Malaria Vaccine Study
SOP	Standard Operation Procedures
USA	United States of America
WHO	World Health Organization
WMA	World Medical Association

OPERATIONAL DEFINITION OF TERMS

Baraza: Public meeting in Kenya held between the citizens and public administrators.

Bodaboda: Conventional term for bicycle and motor cycle taxis commonly used in Kenya.

Community: Social groups of any size with members from similar or diverse backgrounds, ethnicity or race, who reside in a specific locality, share a government or religion, and often have a common cultural and historical heritage, and are sufficiently socially blended to work together for common good. For this study, a community means the group among which the Kombewa Health and Demographic Surveillance System (KHDSS) was implemented.

Community Engagement: The process by which individuals and communities build ongoing, permanent relationships for the purpose of applying a collective vision for the benefit of a community.

Consent: Permission given by research informants to participate in a scientific research. **Community Consent:** Consent given by community leaders and gate keepers to allow household members and individuals to participate in research.

Head of Household Consent: Consent given by the head of the household or their representative, to allow the household and its members to participate in research. **Individual Consent:** Consent given by the individual to participate in research.

Voluntary Informed Consent: Individual choice to consent and freely participate in research after understanding details of the research at hand and without due influence from any other person.

Drug Trial: Health research involving administration of drugs to consenting participants.

Ethical Implications: Either positive or negative effects arising from ethical practices in research, and for this study, consenting practices.

HDSS Researchers: Researchers who participated in the Kombewa Health and Demographic Surveillance System, and who are Key Informants of this research.

Household: A group of people who regularly eat from the same "pot" regardless of whether they live or sleep in the same homestead.

Institutional Review Board: A committee of qualified staff that periodically assess protocols submitted to it by researchers.

International Health Research Ethics: Research ethics applied in health research with an international outlook and structure, on a health phenomenon that take into account adherence to accepted universal ethical principles and guidelines that are meant to protect research participants. In this research, the Kombewa HDSS was studied for international health research ethics focusing on consenting.

Longitudinal Health Research: Research that takes a long time to accomplish, and whose processes including consenting are repetitive over time.

Western Kenya: This is the research site in western region of Kenya where the Kombewa HDSS is located.

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ABSTRACT

Background:. Several studies on informed consent in health research have been conducted, but few have focused on the three levels of obtaining informed consent on a Health Demographic and Surveillance System research, namely consenting the Community, Household, and Individual. Before consenting an individual participant in a Health Demographic Surveillance System, the researcher must obtain consent from two higher levels: The goal of this study was to describe how these three levels of consent, along with various socio-cultural factors, influenced the process of obtaining voluntary informed consent on the Kombewa Health Demographic Surveillance System. The study also looked into the difficulties that the researchers faced. on the Health Demographic Surveillance System and how they used best practices to solve presenting challenges to the consenting process.

Objectives: The study addressed three specific objectives. (i) To describe the process of obtaining informed consent on Kombewa Health Demographic Surveillance System in Western Kenya. (2) To establish socio-cultural factors that influenced the ethical practice of obtaining informed consent on the Kombewa Health Demographic Surveillance System. (3) To explain the challenges and best practices of obtaining informed consent on the Kombewa Health Demographic Surveillance System.

Method: A cross-sectional study, utilizing mixed methods. Simple random sampling was used to select 384 research participants for the questionnaire. In addition, purposive sampling was applied to enlist 12 researchers for key informant interviews. The analysis was done to evaluate consenting and its relationship with socio-cultural factors, with a focus on intrapersonal factors like gender influence, interpersonal factors like household head influence, and community factors like community gate keepers influence. In addition, thematic content analysis was applied to analyse qualitative data.

Results: The three levels of consenting in the Health Demographic Surveillance System influenced the process of obtaining informed consent. Furthermore, the study discovered that researchers on the Health Demographic Surveillance System faced a variety of sociocultural challenges, such as reliance on authority, the influence of household heads, and individual and community expectations to consent to participate in research. Despite the difficulties participants faced and the monotony of re-consenting, researchers made every effort to overcome them. These best practices are presented as lessons for future health researchers to learn from, as well as solutions to challenges. Researchers overcame the challenges by using strategies to obtain voluntary informed consent on the Kombewa Health Demographic Surveillance System, which other health researchers should follow.

Conclusion: The Health Demographic Surveillance System consenting process occurred at three levels, with consent from the top two levels, community and household, influencing individual consenting autonomy.

Recommendation: Health researchers should strive to protect individual autonomy in the Health Demographic Surveillance System by obtaining individual informed consent.

CHAPTER ONE

1.0 INTRODUCTION

1.1: Background of the Study

The focus of this study is on the consenting process in research. One of the most crucial concepts and conceptions in health research ethics is consent. According to Cahana, Samia, & Hurst (2008) and Kulkarni (2014), obtaining individual informed consent is crucial for any study research procedure, since it allows participants to make informed and voluntary choice to participate or not to participate. Various foundational and modern literatures on consenting reveal that the goal of gaining individual informed consent in research is based on the assumption that participants enter research voluntarily and are aware of the risks involved. Previous researchers Xu et al, (2020) and pioneer research ethical recommendations Belmont Report, (1979) have explained how this ought to be done. As stated in international ethical principles; individual informed consent is the preferable method of consenting. The Nuremberg Code (1946), the World Medical Association's Declaration of Helsinki (WMA, 2014), all support this argument (Nuremburg Code 1947,WMA, 2014). According to Alcabes & Williams (2002), all of these standard set of procedures puts constraints on researchers in order to protect the interests of study participants and prevent ethical wrongdoing

The significance of a longitudinal Health Demographic Surveillance System (HDSS) is to better understand health needs and solve health disparities prompted by gross health inequities that exist between the developed and developing worlds to better apprehend health needs and address health gaps. Located mainly in the developing world, particularly in sub-Saharan Africa and Asia, HDSS operate mostly through international research, donor collaborations and partnerships. A Demographic Health

Surveillance System is a geographically defined population under continuous demographic monitoring, with timely production of data on all births, deaths, and migrations Individuals, households, and residential units in a well-defined geographic area, known as a demographic surveillance area, are monitored by demographic surveillance systems. According to Tehmina Ghafur et al (2021), *"although there should be no ambivalence regarding the importance of the health and demographic surveillance System (HDSS), surveillance and research on human populations is beset with a variety of ethical issues. This is particularly true in the area of global health research, which merits attention in health policies related to research ethics"* HDSS research focuses on a wide range of health issues, including drug trials, vaccine studies, and malaria studies, among others. This study was conducted in the Kombewa Health and Demographic Surveillance System, a longitudinally designed international health research site based in Kisumu County, western Kenya.

While there is a need for a HDSS, the ethical pitfalls associated with Health Surveillance Systems must not be overlooked. Because HDSS are generally created to satisfy several aims of conducting research, they are likely to face research ethics issues, according to Carrel& Rennie (2008) & Hinga (2020). The HDSS can, for example, impact population health seeking and treatment decisions, as well as monitor and track population health outcomes across time. As a result of HDSS's many goals and objectives, as well as the protocols and processes that are incorporated in the system, they are likely to defy ethical standards guidelines in their application and unique processes of obtaining individual consent from the research participants.

For scientific study involving humans, voluntary informed consent is universally recognized as a requirement. Specific standards for getting informed consent are outlined in national and international guidelines for ethical behavior in research. Informed consent, according to Marshall et al (2014) is based on an individual's precise comprehension of the study's nature and aim, as well as its possible risks. HDSS research involving populations is fraught with ethical difficulties, which is especially true in the field of global health.

This unique opportunity is an important stance that ought to be investigated. while household level consenting is unlikely to be used in developed countries health surveillance are conducted in underdeveloped countries (Carrel & Rennie, 2008; Hinga A., 2020). In this part of the world, autonomy in decision making mostly lies with the head of the household and rarely are decisions made directly by individuals within households. Researchers have attempted to understand this phenomenon while researching in developing countries. Carrel & Rennie (2008) and Hinga (2020) suggest that in research done in underdeveloped nations, this model of consent should not be used as a substitute for individual consent, and that consent should instead be sought from individual research participants.

Based on these assumptions, this study highlights a number of issues. Is it ethical for a man to provide his family's permission to participate in health-monitoring research? Is it also appropriate to rely on household level consent rather than individual consent in a HDSS? Despite the adoption of ethical norms for obtaining informed consent, putting national and international recommendations into reality might be problematic. Furthermore, health researchers note that in low income settings, it’s not unusual to consent community gatekeepers before consenting heads of households and consenting the individual participant. Is consenting a gatekeeper and household head

culturally sensitivity? Several questions are raised by this study from these presumptions. Is it ethical for a male head of household for example, to consent for his entire family to participate in research? In addition, this research questions if it is correct to rely on household level consenting instead of individual consenting in a HDSS? Could this mean "ethical dilemma" and also imply application of "ethical double standards"? The key question in this study is whether the Kombewa Health Demographic Surveillance System (KDHSS) effectively considers the ethical issue of informed consent while recruiting research volunteers for surveillance.

In addition to the question of individual vs. household consent is the longitudinal nature of the HDSS. This means that if community gatekeepers and household heads provide agreement on behalf of individuals, the individuals who are bound to the same consent for long durations of unjust and unfair research participation. In and of themselves, these long binding periods are unethical and create ethical issues peculiar to HDSS research.

Researchers have identified challenges that are likely to occur as a result of international collaborative health research undertakings, (Akweongo & Nancy, 2006; De Costa et al, 2004). Social, economic among them, include contextual cultural setting concerns, health inequities, inadequate health resources, and underlying power imbalances among collaborating researchers from both developed and developing countries. In a study conducted in the Indian state of Haryana, De Costa discovered that research participants who were interviewed could only opt to participate in research after consulting with their community and family (DeCosta, 2004) . This suggests that the individuals did not have complete power over whether or not to consent to clinical research. Individuals' decisions to participate in research in the Kassena-Nankana district of Northern Ghana were influenced by community

gatekeepers, who played an essential role in the consent process, according to (Akweongo et al, 2006).

Despite increased focus on informed consent in health research, few studies have focused on the process of obtaining individual informed consent on a Health and Demographic Health Research. The Kombewa Health and Demographic Surveillance System, which was the subject of this study, is a longitudinal health research platform in western Kenya. We concentrated on the process of obtaining voluntarily informed consent from individual participants

1.2: Statement of the Problem

Voluntary informed consent is widely recognized as a requirement for human-based scientific research. National and international research guidelines outline specific requirements for obtaining informed consent. When externally sponsored research is conducted in low-income countries, however, several issues may arise when consent from potential participants is sought. It is customary in some communities for male family members to make decisions on behalf of wives and adult children, despite national and international guidelines for ethical research conduct. In other cases, community leaders, chiefs, or elders serve as "gatekeepers," deciding which researchers have access to the entire communities. Individual consent, however, should not be substituted for the decision of community leaders or family heads. Furthermore, while research ethics guidelines state unequivocally that individual research subjects must give their consent, this is not always the case in real-world health research. While it is culturally and socially acceptable for members of western Kenyan communities to listen to and obey gatekeepers for choices and administrative concerns, and that members of the household follow decisions made by the head of the household, this assumption is ethically incorrect. The purpose of this study is to

look into the ethical implications of obtaining informed consent in a Health Demographic Surveillance System (HDSS) in western Kenya, reporting on the consenting process and analyzing the impact of community and household level consenting on autonomous informed individual consent to participate in the HDSS. In a low-income rural setting, the KHDSS, like many other health surveillance systems, faces challenges. These sociocultural, socioeconomic, and individual challenges piqued the interest of this study.

1.3: Justification of the Study

The process of obtaining informed consent for a Health Demographic Surveillance System is unclear, especially from the standpoint of researchers and participants. Little is known about the unique ethical issues that arise during the consent process in a Health Demographic Surveillance System. Previous research on informed consent has stopped at ethical issues without highlighting or uncovering the problem. This study attempted to fill additional gap by exposing the three layers through which the consenting process occurs: community, household, and individual participants. Despite this fact, the entire journey is never thoroughly investigated and dissected.In order to obtain consent from potential research subjects, HDSS researchers must go through these three steps. Unlike most research protocols, which specify a start and end date for consenting activities, demographic and health surveillance can last generations. This study is necessary because it details the entire three-tier consent process for the Health and Demographic Surveillance System. By documenting the process, the findings of this study contribute to a better understanding of the process and implications of obtaining voluntary informed consent on a Health Demographic Surveillance System. This study adds to the body of scholarly knowledge on obtaining consent on health-related issues

1.4: Research Assumption

The study assumed that the process of obtaining informed consent, as well as contextual sociocultural factors, influenced voluntary informed consent on the Kombewa Health and Demographic Surveillance System. The study also assumed that these factors would make obtaining individual voluntary informed consent more difficult.

1.5: Research Questions

1. What do researchers and research participants experience in the process of consenting on the Kombewa health and demographic surveillance system?
2. What are the sociocultural factors that influence consenting on the Kombewa health and demographic surveillance system?
3. What challenges are encountered by researchers in obtaining voluntary informed consent on the Kombewa health and demographic surveillance system?

1.6: Research Objectives

The broad objective of this study was to investigate the process and describe implications of consenting on the Kombewa health and demographic surveillance system?

The specific objectives of the study were to;

1. Describe the process of obtaining informed consent on the Kombewa health and demographic surveillance system.
2. Establish sociocultural factors that influence obtaining voluntary informed consent on the Kombewa health and demographic surveillance system.
3. Explain the challenges of obtaining voluntary informed consent on the Kombewa health and demographic surveillance system.

1.7: Scope and Limitations of the Study

The purpose of this study was to look into the consenting process and how it was carried out on the Kombewa Health and Demographic Surveillance System. The study focused on two research and intervention projects of the Kombewa health and demographic surveillance system, which is located on the outskirts of Kisumu, Kenya, in western Kenya. The study encountered no limitations that could have jeopardized this research.

CHAPTER TWO

2.0 LITREATURE REVIEW

2.1: Description of a Health and Demographic Surveillance System (HDSS)

A Demographic Health Surveillance System, according to the International Network for the Demographic Evaluation of Populations and their Health (INDEPTH), is a geographically defined population under continuous demographic monitoring, with timely production of data on all births, deaths, and migrations Individuals, households, and residential units in a well-defined geographic area, known as a demographic surveillance area, are monitored by demographic surveillance systems. The Kombewa Demographic Health Surveillance System, which covers rural and peri-urban areas adjacent to Kisumu town in Kenya, was the focus of this study.

According to the literature, INDEPTH Network HDSS sites in Sub-Saharan Africa were established and are still operational as a result of international health research collaborations. Methodologically, HDSS sites appear to be indistinguishably positioned between various forms of health activities such as health research and public health (Carrel & Rennie, 2008)(Carrel & Rennie, 2008), but based on available evidence, they can be regarded as non-traditional health-related research. However, there is insufficient documentation of individual informed consent on HDSS characteristics, such as history, socioeconomic context, and current functioning, to provide a solid foundation for understanding and addressing potential ethical issues. It denotes that they are one-of-a-kind. This is why this study chose to investigate the unique consenting processes on the Kombewa Demographic Health Surveillance System. Most demographic health surveillance systems in Africa and Asia today are focused on diseases such as HIV and AIDS, Cholera, Malaria, and Tuberculosis, which manifest negatively in populations and have consistently necessitated

understanding, definition, and intervention attention. To reiterate, the indistinct positions of such health surveillance systems, which frequently address a variety of research, treatment, and population health monitoring goals, means that they are likely to have ethical issues such as voluntary informed consenting (Carrel & Rennie, 2008; Hinga A., 2020). Data collection structures are organized at three levels: the community, the household, and the individual, and it is always difficult to determine who to consent. Is it necessary to obtain consent from each individual or household, or will community consent sufficed?

This study referred to a study conducted in Northern Ghana by Ngom, Debpuur, and Akweongo (2003), in which local cultural values and practices, such as the role of traditional chiefs, influence many aspects of daily life, including participation in research (Ngom et al, 2003). The gatekeeper's decision to grant or deny consent determines whether or not a participant participates in research. A description of HDSS characteristics and ethical issues would aid in determining the best ethics oversight processes for HDSS sites. The HDSS research should be conducted from research ethics perspectives and emphasize individual-level issues such as individual autonomy. These difficult quandaries can only be debated further based on existing studies conducted by many researchers, including (Carrel & Rennie, 2008; CIOMS & WHO, 2002; Coughlin & Ekwueme, 2009; Hinga A., 2020).

2.1.1: The Process of Mapping in Demographic Health Surveillance Systems

The data for this study came from members of households mapped by the Kombewa demographic health surveillance system. Demographic health surveillance systems around the world map and focus their efforts on specific households within the target populations they study. Currently, demographic health surveillance systems mark out

household units for their activities using GPS-based mapping. The HDSS is currently funding health research activities in Kenya and Sub-Saharan Africa aimed at developing new interventions for major diseases of public health importance. For example, it has been used to support the phase 3 RTSS/AS01 Malaria Vaccine trial in Kenya since 2009. For these reasons, the Kombewa demographic health surveillance system served as the foundation for this study's data sources (Sifuna et al., 2018).

2.1.3: Informed Consent

According to the logic that people have the right to know that they are being researched, what the research is about, and what is expected of them as participants, voluntary informed consent is recognized as one of the foundational tenets of ethically responsible research. They also have the right not to be researched unless they expressly consent. The argument is that, while we are not harming people by conducting research on them without their permission, we are wronging them. David Butz (2014) states that Ethical research code has evolved over time and changes are frequently prompted by media coverage of an unethical experiment (Butz, Klik, & Plant, 2014). Ethical codes for research now include specifications that may appear basic, but were not always included in studies. Participation in research and experiments, for example, is required to be voluntary under the Nuremberg Code of 1947. This specification arose as a result of Nazi physicians routinely conducting involuntary experiments in which subjects were coerced into participating. Because of the inhumane nature of tragedies such as Beecher, Tuskegee and Willow brook, Nazi experiments and the 1960-61 Thalidomide birth defect cases, there are a number of ethical principles and guidelines for resolving these troubling problems and questions arising from research involving human participants (Lederer Susan E., 2013). The Nuremberg Code (1948), The Kefauver- Harris Bill (1962), Declaration of Helsinki

(1964), The Belmont Report (1979), and other similar documents, have been the main source of guidance on the ethical conduct of clinical research for the last 50 years (Emanuel, 2000), the CIOMS(2002), WMA, NCE, on and on to date. All these ethics codes agree that need for research must be considered in conjunction with the individual's right to voluntary informed consent, which is based on the principle of respect for autonomy as reinforced by WHO (CIOMS, 2002; WHO, 2004, 2015).

The following three key elements are required for valid informed consent: the provision of information, comprehension of information, and voluntary participation. Informed consent refers to the process by which an individual voluntarily agrees to participate in a research study after the purpose, risks, and alternatives have been thoroughly described. Consent is typically documented by a written, signed, and dated consent form. It is based on the premise that individuals are autonomous agents capable of making self-determined choices (Nuffield Council on Bioethics, 2007).To obtain consent from individuals in such settings, community leaders, elders, administrative authorities, and sometimes religious authorities, as well as family members and influential persons, are likely to influence the decision to participate or not participate in a research study, jeopardizing standard consenting procedures. Barry (1988) addressed the difficulty of translating the concept of autonomy in contexts where personhood is defined by tribe, village, or social group. Different countries have reacted differently to these guidelines. The National Council for Science and Technology was established by an Act of Parliament in Kenya, the context of this research, in 1979. NACOSTI's mission is to "coordinate all research in Kenya and advise the government on all matters related to research" (NCST, 2004).

Consenting processes on a HDSS

In HDSS, obtaining individual informed consent is an ethically difficult process (Carrel & Rennie, 2008). To begin, in order to be effective, HDSS require the participation of the majority of residents and are sometimes associated with the provision of health care. These factors can make it difficult for individuals or households to refuse or withdraw from the HDSS without causing friction with those who do participate. Furthermore, given the longitudinal nature of HDSS and their involvement of entire communities, researchers may find it difficult to decide when and from whom to seek consent (Carrel & Rennie, 2008). Furthermore, given their ambiguous positioning, there is a lack of clarity on the necessity of obtaining informed consent in HDSS. Civil registration systems, which collect data on vital events as well, do not typically seek individual informed consent (Sankoh & Byass, 2012; United Nations, 2018). The wider public health ethics literature, which shifts the focus from individual-level issues such as individual informed consent to population-level issues such as public benefits, accountability, and community acceptability, could provide a general argument against the need for individual informed consent processes in HDSS (Baum et al, 2007; Kass, 2001). For example, some have argued that collecting public health data without informed consent is ethically justifiable if the data is used to improve public health, when burdens on individuals are minimized, when allowing individuals to consent would compromise data quality, or when allowing individuals to consent would compromise data quality or harm others, and when the data is collected by legitimate institution such as a state agency (Alan Rubel, 2012; Klingler et al., 2017; Lee,et al, 2012). According to the International Ethical Guidelines for Human Health-Related Research, researchers should obtain individual informed consent from research participants or seek a waiver

of informed consent from a research ethics committee (CIOMS, 2016; Mariner, 1990). HDSS obtains consent in the home (Carrel & Rennie, 2008; Sankoh & Byass, 2012), Literature reviews of ethics reporting on studies conducted within and outside of HDSS contexts have also revealed gaps in consent process reporting (Chandramohan, et al, 2005; Joshi et al., 2018). Few empirical studies on the ethics of HDSS consent processes, including voluntariness and community understanding of HDSS, have been conducted. Furthermore, the limited empirical research on consenting demonstrates the significant influence of social relations and health inequalities on consenting processes, as described by other health-related research in LMICs (Boga, et al, 2011; Molyneux, et al, 2005; Nyangulu et al., 2019). However, it is not clear how ethical issues for HDSS differ with those for other health-related research, given the empirical and normative uncertainty. To address these uncertainties, context-specific research to describe consenting processes is required (for example, type of consent). Furthermore, ethics scholars have suggested that community engagement could help to address consent issues in HDSS and other health-related research (Molyneux S., 2013; Mondain et al, 2016; Twine et al, 2019).

Most writing on informed consent in Africa focuses on various cultural and social factors that influence informed consent practices, particularly in research settings (Ezeome & Marshall, 2008). Cultural, gender, and social norms frequently influence the consenting process, which can affect the ‘voluntariness' of participants' decisions. Consent is often negotiated collectively (as in a village or household) as well as individually in longitudinal surveillance sites where the entire population is the experimental public (WHO, 2008). Autonomy is a universally applied principle, and it must be negotiated in different cultural contexts. However, in the vast majority of longitudinal studies, informed consent must be obtained at multiple points in time.

(Barry, 1988) addressed the difficulty of translating the concept of autonomy in areas where concept of self is defined by one's tribe, village, or social group in her discussion of AIDS research in Africa. Tribal elders, community leaders, religious authorities, or family members of the research participant may need to be approached to obtain consent from individuals in these settings.

2.2.1: Community Consent to Participate

In general, a community is a group of people who share certain characteristics (Ragin et al., 2008). It frequently precedes a study (for example, people of a certain age or gender), but study selection criteria and procedures may also result in the formation of communities (Bandewar et al, 2010; Montgomery & Pool, 2017). The consent of the community to participate is frequently the first step in determining the location of an HDSS. If no one in the community agrees to participate in the surveillance, another location must be found. However, given the HDSS's intense scrutiny of individual and household lives, community consent is far from sufficient. Is consent at the household level sufficient in terms of respecting individual autonomy? While household-level consent is unlikely to be accepted in surveillance studies conducted in developed countries, the situation in developing countries may be different. Is it, however, ethical for a male head of household to consent to his entire family being monitored? And does preferring household consent over individual consent demonstrate cultural sensitivity or "ethical double standards"? or does it jeopardize people's rights and informed consent (Carrel & Rennie, 2008)

Seeking permission from the community to participate in research is notable in a number of ways. Community leaders play an important role in the consent process as gatekeepers. Only after relevant community leaders have discussed a proposed study

with researchers and given permission for the study to proceed may researchers invite members of the community to participate. Researchers are expected to seek permission from these leaders before inviting community members to participate in their studies. A community is made up of compounds, each of which contains one or more households, each of which houses several generations of a family. Each compound has a "head," who is usually the most senior male in the group. Before approaching members of the compound to participate in a study, researchers must consult with the compound's head. Is it necessary to obtain consent from every individual or every household, or will a single residential unit suffice? (Where values of autonomy may be present in part or entirely) could make this a viable alternative to obtaining consent from thousands or tens of thousands of residents individually (Carrel & Rennie, 2008; Hinga A., 2020). While most research protocols specify a start and end date for consenting activities or sample usage, demographic and health surveillance can last for decades. HDSS administrators must consider whether previously obtained consent for future members of the household counts as consent for future members of the household. For instance, consider 1960s-era studies with continuous household participation, such as Senegal's Niakhar HDSS. Is a grandfather's consent extended to his children and grandchildren even if they were not alive when the study began? (Carrel & Rennie, 2008; Hinga A., 2020).

2.3: Challenges of Obtaining Consent on a HDSS

2.3.1: Challenges Faced by Researchers in the Consenting Process

Cultural, social, and economic factors affect both researchers and the general population in less-developed countries, influencing research ethics. Western culture, which is based largely on individualism, lends itself well to the concept of individual, independent, informed consent. Individuals in Western industrialized countries where personal autonomy is valued are expected to make decisions about research participation for themselves or through designated surrogates. This concept may be less obvious in cultures that place a higher value on the group (tribe, clan, or family), land, or nature over the individual, In contrast, family members or community leaders may play an important role in medical research decisions in many non-western settings (Faden R., 1992). Some of these differences may be misinterpreted as educational barriers, which can be exacerbated by language barriers. The process of obtaining informed consent may be particularly impacted, and certain special circumstances must be defined by expert committees. Strict interpretations of requirements for individual consent may be difficult in culturally diverse resource-poor environments. Early reports by (Ajayi O., 1980; Ekunwe & Kessel, 1984) and others suggested that in certain parts of the world, respect for family and community elders has a strong influence on a community's willingness to participate in research

2.3.2 Challenges Respondent face in HDSS Consenting Process

To protect the autonomy of human subjects in research activities, stringent requirements for voluntary informed consent have been developed, and the close interaction between surveillance systems' individual-level data collection and associated research studies makes the consent process appropriate with HDSS participants. However, given the complexities of the consent process in relation to

surveillance activities involving the concept of autonomy, does consent need to be obtained from every individual or every household, or will consent from a single residential unit suffice? Local cultural values and practices, such as the role of traditional chiefs, influence many aspects of daily life in the Kassena Nankana district of Northern Ghana, including participation in research. Researchers are expected to seek permission from these leaders before inviting community members to participate in their studies (Akweongo P et al., 2003).

2.3.3: Trust in Researchers and their Institutions

According to research conducted in other similar settings, participants frequently trust their researchers to be acting in their best interests when offering them research participation. (Molyneux, Wassenaar, et al., 2005). It is clear that trust, rather than information disclosed during the consent process, influences research participation. This trust is the result of several years of positive outcomes from the health center's work in the community. Although the researchers' trust is well-founded, it may act as a barrier to obtaining genuine informed consent. Members of the community may believe that all research is beneficial and, as a result, fail to consider the risks or burdens of research when deciding whether to participate. However, if the trust is well earned, that is, if research results in improvements in community health, it may facilitate the efficient conduct of relevant research to the extent that community members continue to trust researchers. Ethics review boards and researchers must be vigilant to ensure that such trust is not abused

2.4: Best Practices applied by Researchers in Consenting

The assumption here is that, while practices may present a challenge to investigators in obtaining informed consent, they also provide best practice experiences from which we can learn lessons. Investigators working with diverse populations around the world face numerous challenges, but these challenges do not obscure the best ways for researchers to turn the challenges into notable lessons.

2.5: The Gap Identified in Literature

A review of the literature on the three objectives of this study reveals that there is a knowledge gap that needs to be filled. The aim of this research is to discover the process of obtaining voluntary informed consent in an HDSS. They paused ethical questions without going further to highlight the problem. This study sought to fill additional gaps by exploring the three-tier process of obtaining voluntary informed consent: In the unique contextual and sociocultural factors that not only negatively in a difficult way affect the process of informed consent, but also the best possible practice / basis for the consenting of the research participants, taking into account voluntary participation, autonomy and declaration of Helsinki (1964)

2.6: Conceptual Framework of the Study

The Ecological Perspective: A Multilevel, Interactive Approach

This study was guided by the Ecological Perspective theory by McLeroy, Bibeau and Glanz, (1988)(Mcleroy, Bibeau, Steckler, & Glanz, 1988). The ecological perspective emphasizes the interaction between, and interdependence of, factors within and across all levels of a health problem (Mcleroy et al., 1988). According to these proponents, two key concepts of the ecological perspective help to identify health intervention points: first, behavior both affects, and is affected by, *multiple levels of influence*;

second, individual behavior both shapes, and is shaped by, the social environment (*reciprocal causation*). To explain the concept, (Mcleroy et al., 1988) identified five levels of influence for health-related behaviors and conditions. These levels include: (1) *intrapersonal* or *individual* factors- individual characteristics that influence behavior, such as knowledge, attitudes, beliefs, and personality traits; (2) *interpersonal* factors- interpersonal processes and primary groups, including family, friends, and peers that provide social identity, support, and role definition; (3) *institutional* or *organizational* factors- rules, regulations, policies, that may constrain or promote recommended behaviors; (4) *community* factors- social networks and norms, or standards, which exist as formal or informal among individuals, groups.

This study adopted for use the ecological perspective by (Mcleroy et al., 1988) to present the main thesis of the study that; individual, interpersonal and community factors can influence decisions for voluntary informed consent by research participants. The study does not adopt the entire theoretical perspective by McLeroy, Bibeau and Glanz, but the three levels of influence (individual, interpersonal and community) and not for health practice and promotion but for voluntary informed consent in a health research. Figure 1 below depicts a conceptual framework for this study as adopted from McLeroy, Bibeau and Glanz, (1988)(Mcleroy et al., 1988).

Intrapersonal factors; Gender, age, knowledge of research, socioeconomic status, health status and therapeutic misconceptions are assumed to hold potential for influencing the decision for consent by potential research participants. The conceptual framework assumes further that **interpersonal factors;** Marital status, position in the household and peer pressure can influence people's decisions to participate or not in a health research. People can participate for example, just because a spouse, family

member, neighbor or friend told them to participate or are participating. Furthermore, husbands often do influence the decision for their wives to participate or not in research In addition, **Community factors**; Authority from gate keepers, institutional structures, community health beliefs and illness perceptions, including the fact that a household is mapped to participate, can influence decision to participate or not in a health research. It is also common for people in Kenya to participate in research just because the administrative authority sanctioned the study. These three level proximate factors were studied to establish if and how they influenced consent to participate in the Kombewa HDSS.

Conceptual Framework

Variables and Influence

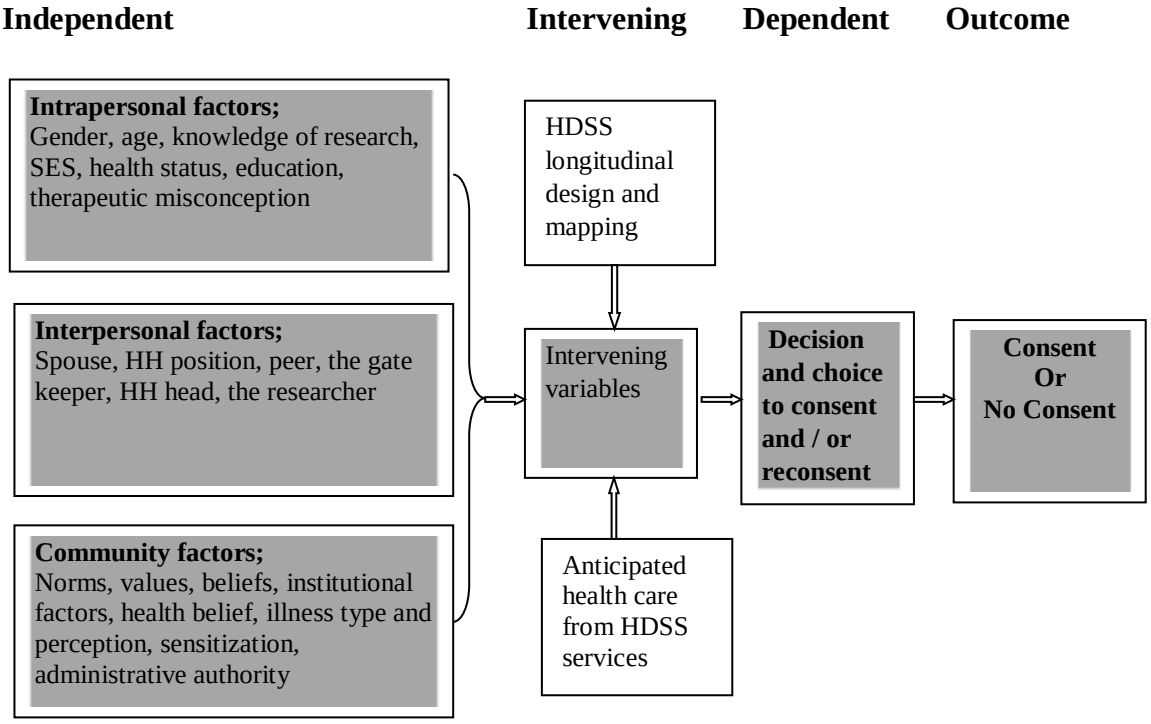

Figure 1: Conceptual Framework *(Source; Researcher as adopted from* (Mcleroy et al., 1988)

To summarize the ideas of the conceptual framework, a set of intrapersonal, interpersonal and community factors assumed as independent variables solely or in combination are liable to influence individual decision to consent / or not, to participate in the HDSS. Notwithstanding, household mapping and the length of the HDSS coupled with expectations of health care services from the DHS have indirect effect on the decision to consent / or not, to participate in the HDSS.

CHAPTER THREE

3.0 METHODOLOGY

3.1: Study Site

This study was carried out at the Kombewa Health and Demographic Surveillance System site (KHDSS). The Kombewa Health and Demographic Surveillance System, is located in Kisumu County's Maseno area in western Kenya. The KHDSS, which covers an area of about 369 km2, grew out of a clinical research center in 2007 and has since established itself as an HDSS research site conducting health research, clinical trials, and disease surveillance.

3.2: Research Design

This is a cross-sectional study that used both quantitative and qualitative data collection methods. To collect quantitative data, a questionnaire was used, while an interview guide was used to generate qualitative data. The researcher assisted with data collection and used trained research assistants to collect questionnaire and interview data.

3.3: Study Population

The population of study comprised of all the persons participating in the Kombewa health and demographic surveillance system; 141,956 persons from 34,718 households. From this study population, those participating in the RTS3 study and the Safety Vaccine Study formed the target population. A sample of 384 households was drawn from a total of 34,718 households, as explained below. From 384 households, one respondent was identified as described below and consented to participate in this research.

3.4: Study Period

Data for this study were collected between June and September 2016.

3.5: Sampling Techniques

Twelve (12) KHDSS investigators were enlisted into this study using purposive sampling. These were researchers who had experience of consenting and studying participants on the Kombewa health and demographic surveillance system, and in particular the two on-going studies. The twelve were identified through the Kombewa health and demographic surveillance system project coordinator, after the researcher explained the research purpose and the eligibility criteria.

For the questionnaire respondents, a random sampling method were used since there were available statistics about the HDSS sampled households and population. To conduct a simple random sample, the researcher first obtained an exhaustive list (sampling frame). The study relied on available statistics of 141, 956 individuals drawn from 34, 718 households to obtain a sample of 384 households using Krejcie and Morgan (1970) sampling formula. Village maps were used to assign households and guide the research assistants during data collection. Using the Kish Grid Method, one individual was selected from each of the sampled household to respond to the questionnaire.

3.5.1: Inclusion Criteria

This study included for the Questionnaire, household members who Lived in Kombewa for more than 5 years and were participating in the RTS3 study and the Safety Vaccine Study of the Kombewa health and demographic surveillance system meaning they must have consented more than three times. In addition, this study also included for KII interviews twelve research investigators / researchers who had conducted health related research on the Kombewa health and demographic surveillance system.

3.5.2: Exclusion Criteria

This study excluded household members in the study area who had been enlisted in the study but were not available at the time of the visit. In addition, new investigators who did not have any consenting experiences in consenting participants more than three times or those not available during the study were excluded.

3.5.3: Sample Size Determination

3.5.3.1: Sample size

The following details the study sample size:

Table 1: Sample Size

Respondents	***n***
Key informant interview with HDSS researchers	**12**
Questionnaire with HH members	**384**

As described in the section above, the sample size for twelve (12) key informants was purposive and this was by census of all the available investigators who had experience of the consenting process on the Kombewa HDSS.

The sample size of 384 members of the household in this study was determined using the Krejcie and Morgan (1970) (Krejcie & Morgan, 1970) formulae and table for sample size determination. Krejcie and Morgan (1970) developed a table for determining sample size given a finite population.

The table derives from the following formulae conjured by Krejcie and Morgan:

The formula below explains how the Table 1was derived.

$$S = X2NP (1-P)/ d2 (N-1) + X2P (1-P)$$

Where; S = required sample size

X2 = the table value of chi-square for one degree of freedom at the desired confidence level

N = the population size

P = the population proportion (assumed to be .50 since this would provide the maximum sample size)

d = the degree of accuracy expressed as a proportion (.05)

Table 2: Table for Sample Size Determination; Krejcie and Morgan (1970)

N-----n	N-----n	N-----n	N-----n	N-----n
10-----10	100-----80	280-----162	800-----260	2800-----338
15-----14	110-----86	290-----165	850-----265	3000-----341
20-----19	120-----92	300-----169	900-----269	3500-----346
25-----24	130-----97	320-----175	950-----274	4000-----351
30-----28	140-----103	340-----181	1000-----278	4500-----354
35-----32	150-----108	360-----186	1100-----285	5000-----357
40-----36	160-----113	380-----191	1200-----291	6000-----361
45-----40	170-----118	400-----196	1300-----297	7000-----364
50-----44	180-----123	420-----201	1400-----302	8000-----367
55-----48	190-----127	440-----205	1500-----306	9000-----368
60-----52	200-----132	460-----210	1600-----310	10000-----370
65-----56	210-----136	480-----214	1700-----313	15000-----375
70-----59	220-----140	500-----217	1800-----317	20000-----377
75-----63	230-----144	550-----226	1900-----320	30000-----379
80-----66	240-----148	600-----234	2000-----322	40000-----380
85-----70	250-----152	650-----242	2200-----327	50000-----381
90-----73	260-----155	700-----248	2400-----331	75000-----382
95-----76	270-----159	750-----254	2600-----335	100000-----384

Source: Krejcie and Morgan (1970:608): N= Population size, and n= sample size

For this study, the table was applied to determine sample size of 384 household respondents. The target population for this study was 141,956 households which are above 100,000. Using the Kish Grid method, from each household, only one (1) respondent was enlisted

3.6: Methods of Data Collection

Two methods of data collection were employed in this study: the questionnaire for members of households and the interview guide with key informants; investigators of the Kombewa health and demographic surveillance system.

3.6.1: Key Informant Interview

Key informant interviews were administered with HDSS researchers and took approximately 45 minutes for one respondent. The questions on the interview guide were categorized according to the study objectives and administered to all the 12 key informants face to face by the researcher. The key informant tool addressed the following variables: the consenting process; researchers' consenting experiences; challenges researchers experienced consenting participants; best practices applied by researchers during consenting. Hence, the key informant tool elicited data to meet the first objective of study; the process of consenting. In addition, the tool addressed the third objective of study; challenges researchers met to obtain consent and best practices they applied to obtain consent.

3.6.2: Questionnaire

The study employed a researcher administered semi-structured questionnaire tool to elicit data from members of the household. The researcher used ten research assistants to collect data and the questionnaire sessions lasted about 40 minutes. The questionnaire was used to collect data on the following variables: participants' socio-demographic characteristics of age, gender, marital status, economic status, level of education and health status. In addition, the questionnaire tool elicited data on sociocultural factors that influence consenting at community level; household level; individual level. Furthermore, the tool offered data about the experiences people

underwent during the consenting process with the HDSS researchers. The focus of the questionnaire was therefore to generate data to meet the second objective of study: sociocultural factors that influence consenting on the Kombewa health and demographic surveillance system.

Below is a matrix depicting the method of data collection and summary of variables each tool addressed:

Table 3: Method of Data Collection and Summary of Variables

Method	**Objective**	**Key variables**
Questionnaire	Contextual sociocultural factors that influence voluntary informed	Levels of consenting: community, household, individual levels; consenting and re-consenting; decisions to consent; reasons for consenting; influences to choice to consent
Key Informant Interviews	The process of obtaining voluntary informed consent on the HDSS, Challenges and best practices obtaining consent	Process of consenting- community level consenting; household level consenting; individual level consenting; experiences of HDSS researchers to seek and obtain consent; challenges of obtaining consent; best practices of obtaining consent

3.7: Pilot Study

A pilot study was conducted using the questionnaire with five (5) respondents and with one (1) key informant, outside the study area but within the Kombewa HDSS. This enabled the researcher to revise the content and the structure of both the questionnaire and key informant tools. The pilot study assured the researcher reliability of the instruments to draw out the same sets of responses from different respondents.

3.8: Study Procedure

Prior to conducting data collection, the ten research assistants received a three day training course to internalize the tools and to form a common understanding of the research protocols. In addition, reconnaissance meetings were held with community leaders to explain the purpose of the study and gain rapport and community entry. Each of the ten research assistants were allocated 38 households/respondents for interview and the researcher interviewed four more respondents. To identify and reach each respondent, the research assistants and the researcher conducted simple random sampling procedure. The researcher first obtained a sampling frame of 34,718 households and assigned a unique number to each household. Using randomly computer generated numbers the researchers selected 384 households. Village maps obtained from the HDSS mapped areas were used to spot and reach each selected household. Using the Kish Grid Method, one eligible individual was selected from each of the sampled household and interviewed. In addition, the researcher interviewed all the 12 key informants. The questionnaire responses were recorded on the hardcopy tool for each respondent. Interview responses were recorded by phone and transcribed into transcripts for content analysis.

3.9: Outcome of Interest

The intended study outcome was decision to consent or not to consent to participate in the Kombewa health and demographic surveillance system. This outcome is also presented diagrammatically, in the conceptual framework that guided this study under chapter two.

3.10: Data Management and Analysis

The questionnaire provided quantitative data which was entered for analysis in the SPSS computer software. Frequencies and percentages were extracted from SPSS outputs and used to summarize data. Descriptive statistics were derived from the software in forms of frequencies and percentages to statistically describe univariate socio-demographic variables. In addition, the Chi square test was subjected to various sociodemographic and sociocultural variables to test for statistical significance as reported in the results section.

Data from the twelve key informants were transcribed verbatim from the recorded memory. Details of each were then typed in and saved as single MS Word files. The data were eventually coded and categorized to interpret meanings from each categorized themes by content analysis. Manually, the researcher categorized data sets that spoke about each theme together, and made interpretations of meanings in each category for each of the themes.

Data analyses of quantitative data sets obtaining from the questionnaire are presented for the first objective of study; the process of consenting. In addition, the second objective regarding the sociocultural factors which influence consenting together with the third objective of study about challenges of consenting and best practices in consenting are presented in the results section using qualitative descriptions, narratives and quotes from key informants. Therefore, the analysis ended up to inform the results of the study and is presented in three sections by each objective of study.

3.11: Ethical Considerations

The researcher sought permission and had the proposal pass through the Moi University Institutional Research and Ethics Committee (IREC) for ethical approval (see attached letter of approval in appendices). The process of informed consent was followed by this study, as spelt out by IREC and the codes of research ethics. The purpose of this study and the study objectives were clearly explained to each participant, and the consenting process dully followed using the two consent forms that are attached to the appendices. Participation in this research was purely on voluntary and autonomous. All potential respondents who were recruited and approached consented to participate in his study by giving informed consent before participation.

CHAPTER FOUR

4.0 RESULTS

4.1: Introduction

This chapter presents findings in response to the central research question: What is the process, the experiences and factors influencing the process of obtaining voluntary informed consent on the Kombewa health and demographic surveillance system in western Kenya. The findings of this study are based on two (2) sources, both of which had a 100% response rate: a household questionnaire with a sample size of 384 and key informant interviews with 12 KHDSS health researchers. The questionnaire primarily provided quantitative information, whereas the key informant tool provided qualitative information. The following is a summary of the chapter: Section 4.1 describes the socio-demographic characteristics of the respondents who took part in the survey; Section 4.2 presents findings from the study's first objective, which is concerned with the process of obtaining informed consent; Section 4.3 presents findings from the study's second objective, which is concerned with contextual sociocultural factors that influence the process of obtaining voluntary informed consent; and Section 4.4 presents findings from the study's third objective, which is concerned the challenges and best practices of obtaining voluntary informed consent.

4.2: Socio-demographic Characteristics of Respondents

The socio-demographic characteristics of respondents were captured and are summarized on table 4.1 below. The table shows frequencies and percentages of the following variables: Gender; age; marital status; religion; occupation; education level; income.

Table 4.1: Socio demographic Characteristics of Respondents

Variables	Variable Category	Scores	
		Frequency	**Percent %**
Gender	Male	56	14.6
	Female	328	85.4
	Total	**384**	**100**
Age in years	21-30	187	48.7
	31-40	105	27.3
	41-50	47	12.3
	51 & above	45	11.7
	Total	**384**	**100**
Marital status	Married	311	81.0
	Single	67	17.4
	Others	6	1.6
	Total	**384**	**100**
Religion	Christianity	308	80.2
	Muslim	58	15.1
	Others	18	4.7
	Total	**384**	**100**
Occupation	Farmer	180	46.9
	Teacher	126	32.8
	Bodaboda	26	6.8
	Unemployed	42	10.9
	Other	10	2.6
	Total	**384**	**100**
Education level	No education		
	Primary	44	11.5
	Secondary	56	14.6
	Tertiary	229	59.6
		55	14.3
	Total	**384**	**100**
Monthly income- Ksh	1,000	78	20.3
	1,000-<10,000	230	59.9
	10,000-20,000	36	9.4
	>20,000	40	10.4
	Total	**384**	**100**

Table 4.1 shows scores of seven socio-demographic characteristics of the questionnaire respondents. There were more females (85.4%) than males (14.6%) who participated in this study. The respondents were relatively younger and married.

A majority of the respondents were farmers and teachers with a secondary education and earned a modest monthly income. Majority of the respondents (51.3%) were over the age of 35 years Twenty-four percent (24%) of the HDSS researchers were engaged on on-going health research studies and Sixty six percent (66%) were engaged on previous HDSS studies. Eight percent (8%) of the HDSS investigators had engaged on the HDSS since its inception in 2007. This means that the key informants were experienced HDSS researchers.

Table 4.2: Objectives and Concepts Investigated

Objective	**SOP**	**Researcher / KI**	**Thematic results**
Document consenting **processes** used by researchers	Researcher meets respondent; reads the consent form details to respondent; asks the respondent decision to participate or not; respondent signs consent form	Community consented; head of household consented and individual consented	Community sensitization; influence of authority; influence of the HH head; best practices of consenting
Establishing how contextual **socio-cultural factors** influence the ethical practice of obtaining voluntary informed consent	Description of various sociocultural factors that influence consenting	Utilization of sociocultural factors to obtain consent	**Intrapersonal factors;** Gender, age, knowledge of research, SES, Health status, and education status **Interpersonal factors;** Marital status, HH position, peer, the gate keeper influence, sensitization levels **Community factors;** Norms, values, beliefs, institutional factors, health/ illness type and perception, sensitization
Explaining the **challenges** of obtaining individual voluntary informed consent on an international longitudinal health study	Description of challenges	Identification and mitigation of challenges to eventually seek and obtain consent	Illiteracy; dependence on authority; influence on HH head; monotony of re consenting; individual and community expectations; therapeutic misconception

4.3: The Process of Consenting Participants on a HDSS

The first objective of this study was to explain the process through which consenting is sought and obtained from individuals to participate in health research. The process of consenting participants was reported to occur at three levels, before the individual finally decides to either consent to participate in health research or not. These are: the community level, the household level and the individual level.

Researchers and participants on the Kombewa health and demographic surveillance system underwent routine step by step processes to seek and obtain consent from respondents to participate in the health research. The KHDSS investigators were able to navigate through the consenting process to seek and obtain consent from individuals to participate in the HDSS health research

4.3.1: Level One - Community Level Consenting

The HDSS community consenting process began with researchers holding a meeting with administration and community representatives to discuss the proposed research. Following this, open community meetings were held on-site to share research program goals and activities. The meetings were held to inform leaders, gatekeepers, and community members about the upcoming HDSS health research. Furthermore, meetings were held with leaders of the local administrative structure at all levels to obtain official permission to conduct research on the community and its members. Detailed discussions and question-and-answer sessions about the proposed health research were held during the community meetings. Once the community leaders were satisfied, they allowed the researchers to further explain the research to community members in forums such as the Baraza (grassroots meeting between administrative Chiefs and community members), and even lobbied the community to

accept the research informally. Community members agreed to the study's eventual completion and granted permission for the HDSS to conduct it.

4.3.2: Level Two - Consent at the Household Level

The second level involved consenting household heads. HDSS researchers obtained verbal informed consent from the heads of households for this study. The reason for this was to encourage eligible members of the household to participate in HDSS health research. After explaining the study to the household head, HDSS researchers asked for permission to list the household. Furthermore, they sought permission from the household's head to allow members of the household to participate in the HDSS health research.

4.3.3: Individual Level Consenting at Level Three

The third level of consenting, the individual level of consenting, was identified as the most critical level of consenting by HDSS researchers because it determines the ultimate point of research participation. Individual research participants in their homes are consented for by field health workers. Individual level consenting entailed obtaining the individual's voluntary informed consent after the head of household agreed to include the household and its members in the HDSS health research.

Despite the fact that individuals' consent is sought to participate, individuals make personal decisions to consent, but their decisions are influenced by community and household level factors.

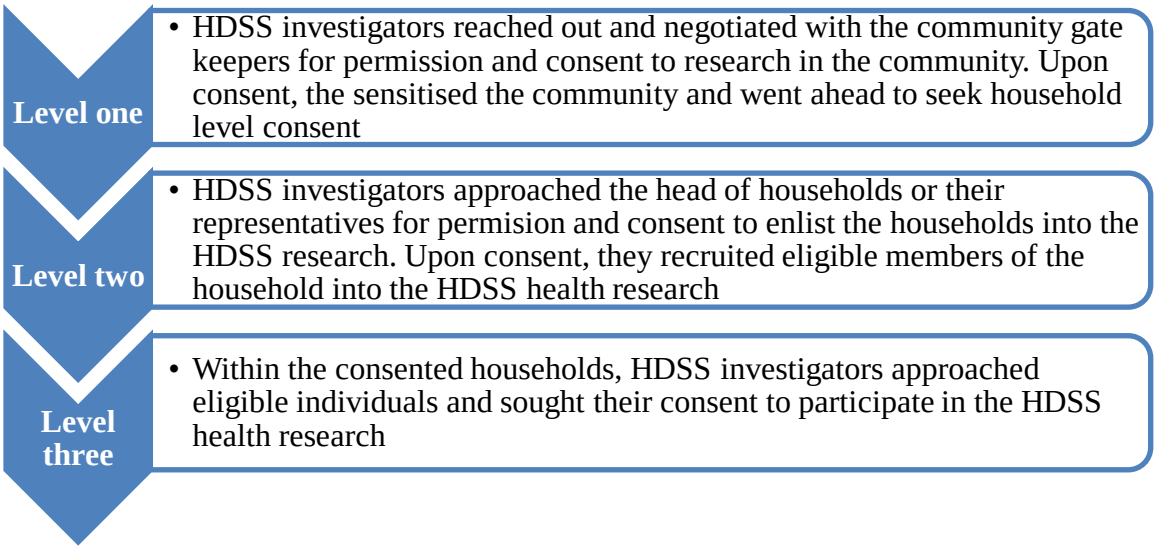

Figure 4.3.1: Three tier levels of consenting

4.3.2: Sociocultural factors influencing the process of obtaining informed consent

The study sought to establish the relationship between various categories of consent and the sociocultural factors. The results are presented in Table 4.2.2

Univariate (Chi square) and multivariate analyses of variance (MANOVA) were used to assess associations within and among the socio-cultural factors and voluntary informed consent. From the findings, intrapersonal ($F(6, 1011) = 9.84$, $p = .001$, Adj $R^2 = .06$), interpersonal ($F(6, 1011) = 6.17$, $p = .001$, Adj $R^2 = .04$), and community ($F(6, 1011) = 45.57$, $p = .001$, Adj $R^2 = .21$) factors significantly impacted on voluntary informed consenting in the study area. We assessed the associations of age, education levels, and occupation. Further, logistic regression analyses were performed to estimate odds ratios and their 95% confidence intervals for each factor while mutually adjusting for other factors mentioned above. A two-sided p value <0.05was considered to be statistically significant. Findings are presented in Table 4.3.2

Compared to men (14.6%), more women (85.4%) participated in this study and that the study reported that married women (81.0%) were influenced by their male spouses

to consent and participate in the HDSS health research. In section 4.2, it is reported that gender significantly influenced consenting ($p < .001$).

Table 4.3.2 Social Cultural Factors Influencing Consenting on HDSS

Pearson Chi-square test of association of sociocultural factors and voluntary informed consenting

Category	Variables	N (%) 384 (100%)	Significance (95% confiden level)
Intra-personal factors	Age	354 (92.19%)	0.005
	Gender	328 (85.4%)	0.001
	Education	348 (90.11%)	0.003
	Income	352 (91.67%)	0.003
	Personal choice	372 (96.88%)	0.004
Inter-personal factors	HH Head Influence	363 (94.53%)	0.001
Community factors	Gatekeeper influence	361 (94.01%)	0.002

Multivariate (MANOVA) analysis results for Sociocultural Factors and voluntary informed consenting

Multivariate Results	F values	Adjusted R^2	P values
Intra-personal factors	(6, 1011) = 9.84	0.06	0.001
Inter-personal factors	(6, 1011) = 6.17	0.04	0.001
Community factors	(6, 1011) = 45.57	0.21	0.001

Table 4.2.2 shows that HH head influence, gender and gatekeeper Influence, influence the voluntary informed consent on the surveillance system, since the p-value is less than 0.05 indicating that there is clear statistically significance evidence to show their influence.

4.4: Challenges of obtaining Voluntary Informed Consent on a HDSS

Challenges of obtaining voluntary informed consent were derived from the reports by the key informants who were researchers on the Kombewa Health and Demographic Surveillance System.

First, the health and demographic surveillance system researchers reported that some individuals who were approached for consent to participate in the HDSS research were uncertain about the purpose of the health research. Some expressed fears that the research was intended to experiment over their health and the health of their children. Researchers had to go a step further to clarify the purpose of the health research and convince this category of potential participants about the benefits and harm of participating in the health research. Most of these were more educated and informed individuals who held considerable knowledge about the rights to participate in health research. Researchers had to neutralize their identities as clinicians and portray themselves as researchers and not health care providers, to convince this category of potential respondents.

Second, some potential HDSS participants were "illiterate", and this made it difficult to read and understand the consent details. Researchers had to express the consent details in their own ways, which again led to varied expressions of the consent form details. This introduced prejudice to lure respondents into consenting to participate in the health research, as captured in the quote below;

> Even if I have to explain and reinforce it verbally, I make sure the participant understands. Some of them cannot read and so the paper will not mean anything to them. Written consent is sometimes just a ritual but it is better verbally given. *Source: Male Key Informant aged 47 years*

Third, health and demographic surveillance system researchers reported that study communities were poor and needy and some participants consented to participate in the health research out of vulnerability and expected financial and health gains. This

expectation was also seen by the researchers as a therapeutic misconception, since the HDSS health research was meant for data collection and not for health care provision. This raises the ethical question in health research how to divorce health care from research. The following quote expresses expectations potential research participants held;

> I know research is good and once I enroll; my child will get good treatment. Source: *Female Questionnaire Respondent aged 38 years*

Fourth, health and demographic surveillance system researchers faced the challenge of expressing the HDSS trial research and their purpose in simple ways that potential participants would easily comprehend. This difficulty is captured by the following quote;

> Ambiguity and confusion surrounding the trial are often confusions surrounding the consent as well. In this regard, some research projects may be too complex. Explaining the specifics, respectively, and slicing the whole information bit by bit becomes more difficult to be done, compared to a trail that is less complicated and with crystal clear tasks. For adequate understanding to take place there is need to adequately be prepared with clear research procedures and consent papers which are later presented to participants. *Source: Female Key Informant aged 38 years*

Fifth, was the challenge arising from the trust for health care providers and for this matter, the health researchers, Potential participants held a belief that health researchers were health care providers who should be trusted by what they say and any health seeking destinations that they potentially offer to research participants. The health and demographic surveillance system researchers reported that this trust makes the process of consenting easier. However, the trust in itself could have "softly coerced" potential participants into yielding to consent to participate in the HDSS health research. As presented on table 4.3 above, 9% respondents reported that researchers influenced consenting, while 31% of the respondents reported the influence made by health care providers.

Furthermore some mothers reported to consent and participate in order for their children to receive health care from trusted health care providers. The researchers reported that as long as the potential participants believed that health research was always accompanied by health care, individuals consented and participated in the KHDSS health research. This position is captured in the following quotes;

> Once it concerns their (respondents') health, they will always consent to be on it (health research) *(Female Key Informant):* As long as it is a study by the centre, they will always like to participate in any study that needs their participation *(Male Key Informant):*
>
> People will be always willing to take part in the study by this institution and it does not matter which study they know because they believe that if it is about us and if something bad happens we will take responsibility *(Male Key Informant)*:

The quotes not only indicate that the individual holds the trust, but in addition, the entire community trusts health researchers and especially the institution the KHDSS affiliated with, which for ethical reasons this research does not disclose.

The trust individuals have for health care providers is best captured by the following quote;

> But sometimes I look over myself and say that with the three injections they knew what they were doing, let me assume they knew what they were doing... because it is their profession and doctors always want the best for us and our children……then as time goes by I have even said let the child be taken, he is in the hands of the people who are experts, -l am not an expert….Doctors will not give us anything that is harmful…Doctors know what is good, when you go to them and they tell you, know that they know it is good. *Female Questionnaire Respondent aged 33 years*

Fifth, researchers from the HDSS were confronted with the dependency on authority, they begin by the HDSS community consenting process, and open community meetings were held on-site to share the goals and activities of the research program. The community leaders, gatekeepers, urge members to participate in the upcoming HDSS health research. As a result, this has an impact on independent decision making or the consenting process. It is not always easy to obtain community participation in an HDSS, and development this necessitates researchers going above and beyond to

clarify that consent is voluntary and is based on the individual rather than the authority.

The authority challenging roles of chiefs and elders, heads of households, and husbands of female prospective participants, on the IC process, is inherent three tier process and social norms to rely on authority. It is therefore unethical for researchers to attempt to circumvent cultural norms or to persuade community members to change their values and practices in any way by changing approach to informed consent. Imposing the researchers' values and principles on local participants is equivalent to ethics dumping, and it has serious consequences for the integrity of the research process as well as the researchers' own integrity.

4.4.1: Best Practices of Consenting by HDSS Researchers

Researchers on the Kombewa health and demographic surveillance system did not only experience challenges in the process of obtaining consent on the health research, they also reported best strategies they applied in the process of obtaining consent.

The Kombewa health and demographic surveillance system researchers had to navigate over three levels of seeking to obtain consent from potential research participants: the community level, because the Kombewa HDSS aimed to study a distinct community and report its health attributes. In addition, they had to navigate through the household level because the Kombewa HDSS was designed to map and survey distinct households and report health. Finally, they had to navigate the individual level, because the Kombewa HDSS ultimately studied to report the health of individuals. This multi-staged level process of consenting is complex to navigate and the professionalism with which the HDSS investigators sought and obtained consent is worth emulating by future researchers. With reference to table 4.1 above,

11.5% of the respondents had no formal education and thus held a poor knowledge of research and especially health surveillance research. The KDHSS researchers had to interpret the consent contents for them, and despite the handicap, they sought and obtained consent.

The KDHSS affiliation to a research institution in western Kenya helped the researchers to consent the community and potential respondents to participate in the HDSS health research. However, researchers were to guard against use of the institutional affiliation as leverage to obtain consent from individuals. Key informants reported that they had to rephrase and interpret to potential respondents the purpose, focus and scope of the HDSS research, so that communities, households and individuals were objectively informed before they decided about consenting. It was not easy to explain that this was not previous or other ongoing research in the area.

> We don't actually use the institution name but each nested study has a distinct name so that we use. *Source: Female key Informant*

Kombewa health and demographic surveillance system investigators admitted that the consenting process was complex and required a clear understanding of the consent process and documents by the researchers themselves before they made the potential participants comprehend them.

> We do not mostly have technical terms associated with trials such as placebo easily translated and understood, because anything given by the doctor to a patient is perceived as medicine. *Source: Male Key Informant*

In addition, most times researchers were required to revisit households and reaffirm because the KHDSS was longitudinally designed, and follow up for health surveillance was part of the KHDSS design. Given this design, the HDSS researchers had to re-express themselves and re-consent individuals they had already consented.

Unless approached carefully, researchers risked making mistakes and assume they already sought consent where it was not, or to re consent where it was not necessary.

The Kombewa Health and Demographic Surveillance System researchers faced some participants that had high expectations to gain from the HDSS and also to receive treatment and health care, by virtue of their association with the health research Potential participants held a belief that health researchers were health care providers who should be trusted by what they say and any health seeking destinations that they potentially offer to research participants.. This became an ethical dilemma for the HDSS researchers. They reported that it was difficult to make participants engage in research, without any reasonable health benefits. They reported that it was hard to repetitively over a long time ask about the health of an individual, without offering them health care. The HDSS researchers manage this professionally by making referrals of health needy participants, without jeopardizing the processes and objectives of the HDSS health research. Participants used consent forms as tickets to seek treatment of their children. *: Female Key Informant.*

Lastly, Kombewa Health and Demographic Surveillance System researchers reported that they faced individuals and communities that were research fatigued first because of the longevity of the HDSS and also because the study area is a nexus of previous and current health research. Notwithstanding, HDSS researchers managed to consent and recruit participants in the Kombewa HDSS research successfully owing to their research experience, tenacity and professionalism. Despite encountering challenges, the HDSS researchers offered best practices that addressed these challenges. The table below shows some of the ethical dilemmas they faced and how they attempted to resolve them:

CHAPTER FIVE

5.0 DISCUSSION

The purpose of this study was to investigate and describe the process of obtaining consent and also to explain the challenges faced by researchers during the consenting process on the Kombewa health and demographic surveillance system.

Voluntary informed consent is universally accepted as a prerequisite for human-based scientific research. Specific requirements for obtaining informed consent are outlined in national and international guidelines for ethical research conduct. Standards procedure , such as that requiring individual informed consent be given voluntarily by competent participants, be met whatever the cultural context within which research is conducted (Kamuya, Marsh, & Molyneux, 2011; Marshall et al., 2014).

However, the levels of authority structures and approaches to the participant the position of an individual in the household influence the process of obtaining individual informed consent.The three tier process of consenting by researchers on a Health and demographic surveillance system poses a challenge in obtaining autonomous and voluntary informed consent. In this study, it was established that individual autonomous voluntary consenting was influenced by both community and household levels of consenting that were requisite in HDSS research. The study established that when the community leaders agreed and gave permission for a health research, and at the household level, the head of the household agreed that members of their household will participate in health research; it was almost given that the individual was most likely to consent and assent to participate in the health research.

This finding concurred with Margaret and Reenie (2008) Hinga (2019), Tehmina Ghafur et al (2020)(Carrel & Rennie, 2008; Ghafur, Islam, Alam, & Hasan, 2020; Hinga A., 2020), who argued that the complications in the consent process specific to surveillance activities related to conception of autonomy, the position of individuals within households and communities. It was clear that, the head of household influences people within the household to consent to health research.

In a study in the Kassena-Nankana District of Northern Ghana (Akweongo, & Kass , 2006) reported that community leaders, local authorities and household heads influenced individuals' decisions to participate in research. Furthermore, while reporting findings of a study in rural India, DeCosta A. et al, (2004) argued that there were complexities involved in obtaining informed consent to participate in clinical research and, as a result, people made decisions to participate in clinical research that were dependent on the decision made by the house holds and community.

In this study, the same conclusion was drawn from the findings presented in section 4.2, which demonstrated that, while the individual eventually agreed to participate in the Kombewa HDSS, their decision was influenced by the acceptance of the head of household to include household members in the HDSS research. Also, the community's blanket permission to have members of the community participate in the HDSS health research influenced the decision. This goes against the principle of informed consent, which is enshrined in national and international codes. Research findings by Hinga (2018) and Carrel & Reenie (2008) Tehmina Ghafur et al (2020) (Carrel & Rennie, 2008; Ghafur et al., 2020; Hinga A., 2020), reported that the household head and community gate keepers including public administrators held influence over individuals under their jurisdiction to consent in health research. Hinga A., (2020) while reporting findings from health and demographic surveillance system

research conducted in Nairobi and Kilifi Kenya, reported how community leaders provided community-level consent, which culminated in "interfering/influencing" with voluntary individual consent.

This finding corroborated reports by other researchers on the same subject including (Benatar, 1994; Brear M., 2018; Doumbo, 2005; Emanuel et al., 2000; Fairhead, Leach, & Small, 2006; Qiu, 1993). It is appropriate in some African settings to seek permission from gatekeepers of specific communities, such as village elders and chiefs, to conduct research with a specific population, but such permission is not a substitute for individual consent (Akweongo Patricia, Kass Nancy, 2006; Diallo et al., 2005; Faden R., 1992; Molyneux, Peshu, & Marsh, 2005a; Nyika, Wassenaar, & Mamotte, 2009). Proxy decision-making is inconsistent with national and international guidelines for ethical research conduct, which recognize individual informed consent to be given voluntarily by competent participants, must be met regardless of the cultural context in which research is conducted. In the KHDSS the three tier process of obtaining informed consent interferes with the principle of respect of persons.

Owing to this form of consenting process, this study also looked at the implications of social and cultural factors on people's decision to consent. The influence of male spouses on female spouses in decision making has been widely reported by studies in patriarchal societies, and this study's findings were no exception. Many respondents indicated that they did not make decisions on their own behalf, but were subject to decisions made on their behalf by the community leader or, at a closer level, by their family head, most often a husband or father. When respondents were asked who influenced their decision to consent, it was revealed that their decision to consent on the HDSS was influenced by the researchers; the spouse; the gatekeepers' authority;

health workers, and self-choice. Which is common in developing-country studies, this has gotten a lot of attention in other places, such as Japan, Nigeria, Botswana, and China(Benatar, 1994; Brear M., 2018; Doumbo, 2005; Ezeome & Marshall, 2008; Fairhead et al., 2006; Qiu, 1993).

From the findings this study corroborates with other studies and yes, women's participation in research is influenced by interfamily and gendered relationships. Some women in an Indian trial, for example, did not enroll because they were unable to make an independent decision (Gitanjali et al, 2003). Other women withdrew from a trial in Chile due to "pressure from partners" (Sánchez et al, 2001). Women in Kenya (Ngare, 2007), Nigeria (Bhan, Majd, & Adejumo, 2006; Osamor & Kass, 2012) (Bhan, Majd, and Adejumo 2006; Osamor and Kass 2012), and Uganda (Loue, Okello, and Kawuma 1996) refuse to participate if their husbands will not allow it. In a Kenyan trial involving children, mothers believed it was normal for the father to make decisions about a child's participation, so they expected the father to make decisions about a child's participation. Mothers are simply carrying out their social responsibilities (Kamuya, Marsh, & Molyneux, 2011). In contrast, a collaborative randomized trial in India concluded that, despite practical constraints, it was deemed a respectful approach to obtaining informed consent (Gitanjali et al., 2003).

Decosta and colleagues (2004) in another study from Sri Lanka discovered that decision-making is more family-centered than individualistic, and that integrating international requirements and local practice is difficult (Sariola & Simpson, 2011). According to a study conducted in Dhaka, 76 percent of researchers believe it is critical to consult the husbands for consent in the case of married women enrolled in research(Hossain Talukder, 2016). Similarly, while 84 percent of trial participants in rural India stated that their decision to participate in a trial was their own, only 36.8

percent did so independently (DeCosta A., D'Souza N., Chhabra M. S., Shihaam I., 2004). Table 4.3 in the results section shows the percentage scores for these reported factors that influence individual consent.

Referring back to chapter two, the conceptual model, several independent variables were proposed to likely influence the dependent variable of consenting. Age, gender, education level, income, and personal choice were proposed as intrapersonal independent variables. Furthermore, interpersonal level (influence by household head) and community level (influence by community gatekeepers) variables played a significant role. Additionally, confirmation of the independent variables' influence on the dependent variable, as proposed in the conceptual model, allows the researcher to assert that individual consenting on the HDSS was influenced by factors that reside at the three tiers of the consenting process: community, household, and individual levels. This study also found that sociocultural factors influenced people's willingness to consent to and participate in the KHDSS.

Participants should be well informed about the study and made to understand or be knowledgeable about health research, the potential risks and benefits of their participation, and that they will be participating in research rather than therapy (Gitanjali et al., 2003). Researchers influenced consenting because people trusted them and believed that health research came with much-needed health care. As a result, some households and individuals agreed to participate in health research in order to benefit from the anticipated family healthcare. Several studies by different researchers attest to the fact that research participants in health research from low-income backgrounds frequently had high expectations of gaining benefits from the research in which they participated(Kamuya et al., 2014; Molyneux, Peshu, & Marsh, 2005b)

The research community members who included the participants held high personal and collective expectations for health care, especially for their children. This fact is reminiscent of a wide range of health research that report high research participants' expectations from research and researchers. Notwithstanding, it is not surprising that most health and demographic surveillances in Kenya and around the world occur in low income and poor populations (Carrel & Rennie, 2008; DeCosta A.et al, 2004; Hinga A., 2020; Kamuya et al., 2014). After all, these poor settings are the very communities whose health parameters need to be assessed and reported about to instigate health intervention. This means that the ethical dilemma of researching in vulnerable communities with high expectations of benefits still remains unresolved. This study concurs with the findings of (Nelson, Beauchamp, & Miller, 2011), who described a model of voluntariness in consent that included internal and external influences as well as a constraining situation.

We discovered a significant relationship between education/college and consenting in terms of personal choice. In other words, educated participants were more likely than uneducated participants to choose to consent individually without influence from the subjective other. Social and gender norms can also influence voluntariness. Such factors are difficult to account for in consent evaluations, as evidenced by findings from Ghana and Mali.)(Akweongo Patricia, Kass Nancy, 2006) In addition to establishing a relationship between variables and explaining the three levels of consenting on the Kombewa HDSS, this study revealed a number of sociocultural factors that influenced individual consenting. This included both male dominance and female subordination (Clark, 2008; Way, 2013). According to these researchers, research expectations and male dominance interfered with genuine individual consent in low-resource countries. As a result, sociocultural norms and beliefs are thought to

have defined and permeated the daily lives of typical patriarchal rural ethnic communities in Kenya and elsewhere in Africa (Adebamowo et al, 2007; Doumbo, 2005).

The KDHSS faced a number of challenges in obtaining individual voluntary informed consent from both investigators and participants. The investigators reported the complexity of participant comprehension and explaining the KHDSS health study to participants in order for them to understand. Further research revealed that participants' illiteracy influenced their comprehension of the health research in which they were to participate. There were also issues with therapeutic misconception and respondents' expectations of health benefits. Concerns were also raised when senior community members purported to consent to research on behalf of a community rather than taking into account their role as community recruitment authorizers. (Akweongo Patricia, Kass Nancy, 2006). Economic constraints also lead to participants wanting to join studies in order to receive study-related benefits, even if they have significant reservations or only a limited understanding of some aspects of the research. (Leach et al., 1999).

Challenges to consenting are widely reported in literature and studies by (Allen, Joly, & Moreno, 2019) and (Petryna, 2015) Misconceptions about research are common in developing countries, owing to factors such as low literacy skills, limited access to health care, and a lack of familiarity with clinical research and consent procedures. The findings of this study agree with those of previous researchers such as Gitanjali et al (2003), in a study in Haryana India, who reported that getting a meaningful and ethical informed consent in poor settings becomes challenging due to differences, health needs, education, cultural values and customs in developing countries. In a nutshell, there is an overall difficult responsibility: obtaining ethical informed consent

from subjects who may be illiterate in the sense that they lack knowledge of scientific research but are not unable to choose not to consent due to therapeutic misconception and may have no prior concept of clinical research. According to the literature, the process of obtaining voluntary consent can be interfered with by this therapeutic gain myth. This was a problem also seen in the KDHSS. Hence, our study corroborates with other studies with the same views as documented in both developing and developed countries. For example, in a study conducted in a Brazilian clinic, all of the women interviewed stated that they enrolled in the study because they "thought that the contraceptive being offered would be good for them" (Hardy et al, 1998). Because of financial constraints, participants may want to join studies in order to receive study-related benefits, even if they have significant reservations or only a limited understanding of some aspects of the research (Leach et al., 1999).

Despite this, the researchers demonstrated tenacity in enrolling and consenting participants without coercion, particularly by emphasizing the HDSS's purpose and benefits. The HDSS researchers navigated the three tiers process in an ethical manner, avoiding the challenges of expectations, community fatigue, and the complexities of consenting to a longitudinal health study.

These best practices are presented here as lessons for health researchers to learn from, as well as solutions to the challenges that the researchers faced, as described above. Researchers overcame the challenges by employing strategies similar to obtain individual voluntary informed consent, which other health researchers should emulate.

The KHDSS researchers provided information to potential participants. A step-by-step approach to obtaining consent ensures that the individual understands the information provided and voluntarily agrees to participate in an ethically sound consent process as stipulated by Ezome and Marshall (2008), this best practice was supported by Kombewa researchers who saw the importance of preserving individual autonomy.

Furthermore, because the KHDSS was designed to be longitudinal, and follow-up for health surveillance was part of the KHDSS design, researchers were frequently required to revisit households. Given this design, the HDSS researchers were forced to re-express themselves by re-consenting previously consented individuals. They approached this cautiously, taking care not to make mistakes by assuming they had already sought permission where they had not, or to re-consent where it was required.

The Kombewa Health and Demographic Surveillance System researchers encountered some participants who had high expectations of benefiting from the HDSS as well as receiving treatment and health care as a result of their involvement in health research. This created an ethical quandary for the HDSS researchers. Rather than providing health care, they provided clarification of the research objective. However, they reported that it was difficult to persuade participants to participate in research when there were no reasonable health benefits. They also reported that it was difficult to repeatedly ask about an individual's health without offering them health care over a long period of time. The HDSS researchers handle this professionally by referring participants in need of health care without jeopardizing the processes and objectives of the HDSS health research. Despite the fact that the KDHSS researchers had to interpret the consent contents for them, they sought and obtained consent.

Finally, Kombewa Health and Demographic Surveillance System researchers reported that they encountered individuals and communities who were research fatigued, owing to the HDSS's longevity and the study area's nexus of previous and current health research. Despite the fact that they reiterated overarching research benefits, HDSS researchers were able to successfully consent and recruit participants in the Kombewa HDSS research due to their research experience, tenacity, and professionalism.

The process of obtaining individual Voluntary informed consent on KHDSS was influenced by the three tiers that the researchers went through to get to the individual and obtain consent. As indicated by respondents, the decision to consent was made on their behalf by the community leader or, at a closer level, by their family head, most often a head of the house hold, trust in the researchers and need for health care. This Social relationships in consent, has gotten a lot of attention in other countries, including Japan, Nigeria, Botswana, and China. Benatar, 1994; Brear M., 2018; Doumbo, 2005; Emanuel et al., 2000; Fairhead, Leach, & Small, 2006; In addition to the question of individual vs. household consent is the longitudinal nature. This means that if community gatekeepers and household heads provide agreement on behalf of individuals, the individuals who are bound to the same consent for long durations of unjust and unfair research participation. In and of themselves, these long binding periods are unethical and create ethical issues peculiar to health.

Despite this, the researchers demonstrated tenacity in enrolling and consenting participants by employing strategies and best practices which other health researchers should emulate.

Strength and limitation of the study

The most serious limitation of this study was recall bias; the participants had been consenting for a long time and were very likely to have recall bias. Furthermore, the participants respected the HDSS and research researchers who had been with them for a long time and answered in a way that would maintain the relationship. They did, however, understand the term informed consent as a result of repeated research in the area, which was a study's strength.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1: Conclusion

Consent for the Kombewa Health and Demographic Surveillance System was obtained at three levels: community, household, and individual. Individual consenting was influenced by community consent and consent by the head of the household, interfering with the individual autonomy of research participants to consent voluntarily. Individual consent was determined by intrapersonal factors such as age, gender, education level, and personal preference. Consent to participate in health research on an HDSS occurs at three tier levels: community, household, and individual. This means that in order to obtain valid individual informed consent, researchers in similar health research contexts should consider the ethical implications posed by the three-tier consenting process. Individual informed consent should be obtained by health researchers to protect individual autonomy in the Health Demographic Surveillance System. Understanding research context, social norms and social relationships to influence voluntariness of consent processes is important and should be checked.

6.2 Recommendations

- Researchers and research participant should strive to uphold and guarantee the principle of respect of persons by obtaining individual informed consent
- The researchers in such settings should adhere to SOPs consent every participants and re consent at every visit.

IRBs should consider coming up with a way of mitigating the community gatekeeper’s influence on individual informed consent

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APPENDICES

Appendix 1: Key Informant Guide for HDSS Investigators CONSENT FORM

Consent Form for Key Informant Interview.

Title: Ethical Implications of Voluntary Informed Consent on a Longitudinal International Health Research in Western Kenya

Researcher: Audrey Nafuna Mukhwana; Department of Behavioral Sciences, Moi University. P.O Box 4606, Eldoret.

Purpose: The purpose of this study is to establish the Ethical Implications of Voluntary Informed Consent on Kombewa Health and Demographic Surveillance System in Western Kenya

For KII- Invitation: You are therefore being invited to participate in this research since you have been participating / a researcher on KDHSS and you have had a chance to participate in a research previously or currently.

Participation: Participants will be chosen based on whether they have previously consented to participate in research or are currently consenting to do so. They must also agree to participate in my research in order to be considered. Procedure: The research will take place in your areas and you do not need to move out of your office if you accept to participate you will sign the consent form to show acceptance before we begin the interview. The interviews may take between 30-45 minutes of your time. Participation will be free with no compensation.

Risks: I do not think there will be any risk to you from participating in this research.

Potential Benefits: There will be no benefits to you during participation in this research.

Voluntary Participation Statement: Your participation in this research study is completely voluntary. You do not have to participate if you do not want to. You may also stop participation at any time if you do not want to continue.

Privacy and Confidentiality: During your participation, your name will not be given to anyone other than research team. The questionnaires will be coded so that your name does not appear anywhere. All the information collected from you or about you will be kept confidential to the fullest level allowed by the law. In rare circumstances, specially authorized university or government officials may be given access to our research records.

Research Study Results: If you wish to learn about the results of this research study, you may request for that information by contacting;

Contacts: Audrey Mukhwana Mobile: 0716121375 / Email: nafunanamanda@gmail.com

The same contacts may be used in case you have any questions regarding this study.

Consenting: I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks and discomforts as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

……	…….	……
Subjects name:	Signature	Date
…….	……	……
Name of person obtaining consent	Signature	Date

1: Guide for Key Informant Interviews

DC tool	Objective	Sample size
KII	1 & 3	12

Qn1. What is the process of consenting participants on the KDHSS?

- Who were consented on the KDHSS? HH heads. HH members. Who else?
- How did you/ researchers consent participants at the initial contact?
- Did researchers re-consent same respondents latter? After how long was this? How was the process of re-consenting?

Qn2. What are the experiences of researchers consenting on the KDHSS?

- What were your experience consenting participants? Were you personally involved? How did you do it? Did you consent participants directly or through others? Who did you consent directly? Who did you consent through others? Who were the others?

Qn3. What are specific and contextual ethical challenges encountered by researchers in obtaining voluntary informed consent on the KDHSS?

- What challenges do researchers face consenting on the KDHSS? What challenges have you faced?
- Narrate one example of a challenge faced by researchers in the consenting process?
- What are researcher related challenges in consenting on the KDHSS? Training? Bias? Shortcutting? Language barrier?
- What are sociocultural challenges in consenting on the KDHSS? Language barrier. Gender? Age differences? Influence of husbands, parents, and fathers/mothers in-law, the subjective other. Influence of authorities, community leaders, religious leaders, peer, CHC members. What are other social and cultural influences you experienced?
- What are logistical challenges in consenting on the KDHSS? Planning, contact times, appointments, participant expectations, therapeutic misconceptions. Seeking authority, sensitization, rapport and community entry. What else did you experience logistically?

- What are institutional challenges in consenting on the KDHSS? Influence of authorities. Goodwill from community gate keepers. Goodwill and support from the project. Support from the project sponsors, project administrators. What else posed structural challenges?
- What are the challenges experienced from respondents consenting? Language barrier. Misconceptions. Expectations. Failure to understand purpose of research. Outside influences. What else?
- What are the challenges re-consenting on this longitudinal study? Fatigue (researcher/informant). Loss of informants. Follow ups. Disinterest from informants. What else?
- How did the researchers address the challenges they faced in the process of consenting on the KDHSS? Explain how for each type of challenge mentioned above *(Ask this repeatedly for each challenge).*

Qn4. What are the best practices in the consenting process by researchers on the KDHSS?

- What worked well with IRBs including IREC regarding consenting on the KDHSS?
- What worked well with the consenting process on the KDHSS?
- What worked well from researcher skills & training? What about the structure of research team?
- What worked well by institutional identity (CDC KEMRI/ USAMARU?
- Are there expectations by researchers and participants from the KDHSS? What expectations? How have the expectations influenced consenting?
- Has the internationality of the KDHSS influenced consenting? How exactly?
- Narrate one good experience in consenting process from the KDHSS.
- How do KDHSS researchers beneficially interact with foreign researchers to achieve best consenting practices? Cultural sensitivity and compatibility. Adherence to universal guidelines, regulations and procedures for obtaining voluntary informed consent.

Appendix 2: Questionnaire for Household Members

Consent Form

Title: Ethical Implications of Voluntary Informed Consent on a Longitudinal

International Health Research in Western Kenya

Researcher: Audrey Nafuna Mukhwana; Department of Behavioral Sciences, Moi University. P.O Box 4606, Eldoret.

Purpose: The purpose of this study is to establish the Ethical Implications of Voluntary Informed Consent on a Longitudinal International Health Research in Western Kenya

For KII- Invitation: You are therefore being invited to participate in this research since you have been participating / a researcher on KDHSS and you have had a chance to participate in a research previously or currently.

Participation: Participants will be selected on the basis that they have previously participated in research or are currently participating in one. They also need to accept to participate in my research for them to be included. On the other had the exclusion criteria includes those who have never participated in research as well as those who refuse to be included in this study.

Procedure: The research will take place in your areas and you do not need to move out of your office/ home those who will have accepted to participate will be given the consent forms to fill first followed by the in-depth interview between them and the researcher. The interviews may take between 30-45 minutes of your time. Participation will be free with no compensation.

Risks: I do not think there will be any risk to you from participating in this research.

Potential Benefits: There will be no benefits to you during participation in this research.

Voluntary Participation Statement: Your participation in this research study is completely voluntary. You do not have to participate if you do not want to. You may also stop participation at any time if you do not want to continue.

Privacy and Confidentiality: During your participation, your name will not be given to anyone other than research team. The questionnaires will be coded so that your name does not

appear anywhere. All the information collected from you or about you will be kept confidential to the fullest level allowed by the law. In rare circumstances, specially authorized university or government officials may be given access to our research records.

Research Study Results: If you wish to learn about the results of this research study, you may request for that information by contacting;

Contacts: Audrey Mukhwana Mobile: 0716121375 / Email: nafunanamanda@gmail.com

The same contacts may be used in case you have any questions regarding this study.

Consenting: I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks and discomforts as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

……	…….	……..
Subjects name:	Signature	Date
…….	……	…….
Name of person obtaining consent	Signature	Date

DC tool	Objective	Sample size
Questionnaire	1, 2 & 3	384 HH members

Section A- Socio demographic Characteristics of Respondents

1. Sex 1. Female |___| 2. Male |___|
2. Age (Years) |___|___|
3. Marital status

    1. Married |___|
    2. Single |___|
    3. Divorced |___|
    4. Separated |___|
    5. Widowed |___|

4. Education

    1. Primary |___|
    2. Secondary |___|
    3. College |___|
    4. University |___|

    5. Other (Specify)……

5. Religion

    1. Christian |___|
    2. Muslim |___|
    3. Traditional |___|

    5. Other (Specify)……

    5. Occupation

6. 1. Farmer |___|

2. Teacher |___|
3. Bodaboda |___|
4. Unemployed |___|

5. Other (Specify)……

7. Income (In Ksh. per month)

    1. < 1000 |___|
    2. 1000 – <10000 |___|
    3. 10000 - <20000 |___|
    4. >20000 |___|

    5. Other (Specify)……

Section B- Individual factors Influencing VIC

8. When did you consent to participate on the KDHSS? Year- |___|___|___|___|
9. Did you voluntarily consent to participate on the KDHSS? 1. Yes |___| 2. No |___|
10. Did anyone ask you to consent on the KDHSS?
    1. Yes |___| (Specify who)……
    2. No |___|

11. If yes (Qn. 10), for what reasons were you asked to consent to participate on the KDHSS? ……
12. Did you have enough information about the KDHSS at the time you consented to participate?
    1. Yes |___| (Specify what info)……
    2. No |___| (Specify what
13. What reasons made you to consent to participate on the KDHSS?
    1. Own interest |___|
    2. Health reasons |___|
    3. Benefits |___|
    4. Other (Specify)……

Section C- Interpersonal factors Influencing VIC

14. Who did you first get information about the KDHSS?
    1. Researcher |___|
    2. Other (Specify)……

15. Who influenced your participation on the KDHSS?
    1. Self |___|
    2. No One |___|
    3. Husband/wife |___|
    4. Other family member |___|
    5. Relative |___|
    6. Neighbor |___|
    7. Friend |___|
    8. Health provider |___|
    9. CHW |___|
    10. Authority/administration |___|
    11. Other (Specify)……
16. How did they influence you?
    .....

Section D- Community factors Influencing VIC

17. Why did you decide to participate on the KDHSS (*Read out and select as many*)?
    1. Self decision |___|
    2. Husband/wife decided |___|
    3. Our House was mapped/marked |___|

4. Authority/administration decided |___|
5. Friend/neighbours decided |___|
6. Health provider/CHW decided |___|
7. Because it was a health research
8. Because researchers came from the Hospital/University |___|
9. Other (Specify)……

18. Which people should participate in health research?
    1. Anyone |___|
    2. People with a health problem/sick |___|
    3. People who need health assistance |___|
    4. Other (Specify)……

Section D- Challenges to VIC

19. How long ago did you consent to participate on the KDHSS? Months |___|___|
20. For how long have you been participating on the KDHSS? Months |___|___|
21. How many times have you consented to participate on the KDHSS? |___|___|
22. Each time you have participated in research with the KDHSS, have researchers consented you each time?
    1. Yes |___| Ask how many times consented |___|___|
    2. No only once |___|

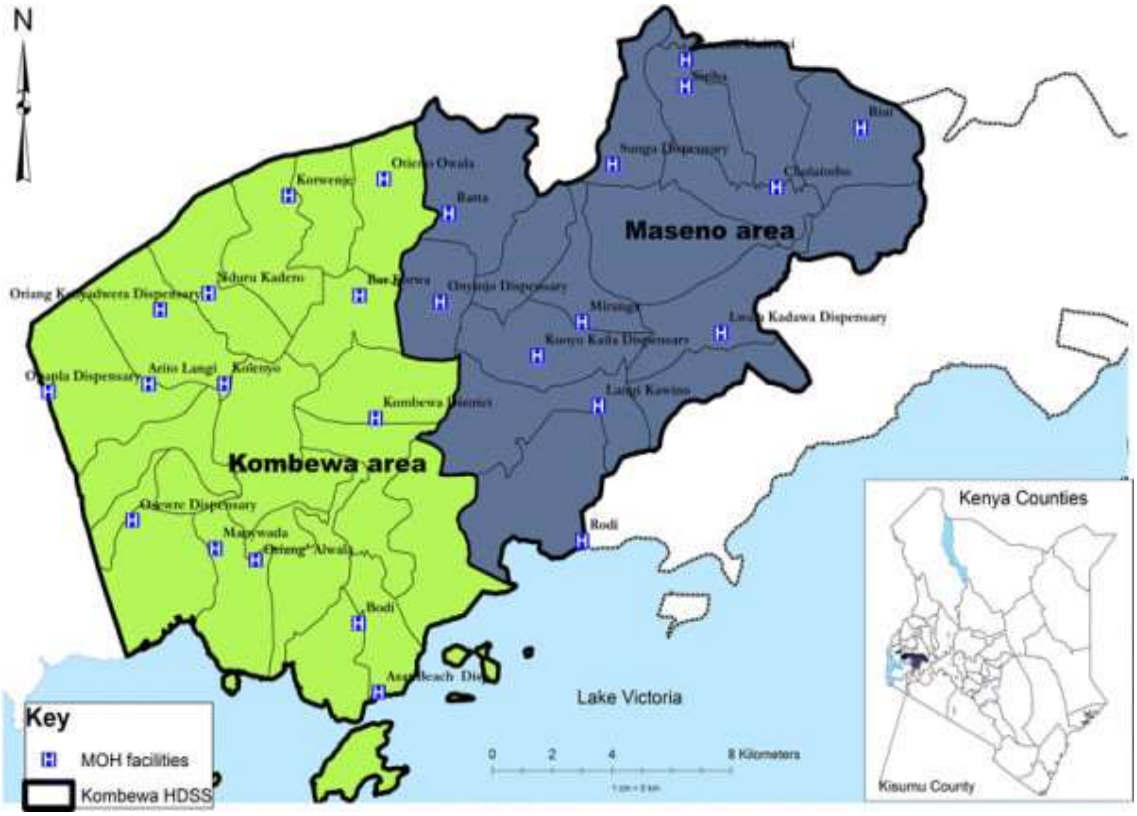
Appendix 2: Study Work plan and Time Frame

Activity	**May 2014**	**June 2014**	**Feb 2015**	**June 2015**	**Aug 2015**	**March 2016**	**June/July 2016**	**July/august 2016**
Concept idea	**X**							
Proposal writing	**X**	**X**						
IREC approval						**x**		
Reconnaissance and pilot						**x**		
Data collection							**x**	
Data analysis							**X**	
Thesis write up								**X**
Submission of MSc. Thesis								**X**

Appendix 3: Study Budget

No.	ITEM	TOTAL (Ksh)
1.	Laptop, printer & stationery	80,000
2.	Photocopy & binding	15,000
3.	Literature search	20,000
4.	Analysis of data	18,500
5.	Travel & accommodation	40,000
6.	Honoraria investigator & assistants	30,000
7.	Contingencies 10%	18,850
8	Digital audio recorder	6,000
Total		**228350**

Appendix 4: Map of Study Site- Kombewa HDSS



Appendix 5: Mapped KDSS Household

Mapped household code number- Kombewa HDSS

Appendix 6: IREC Approval Letter

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/217
Approval Number: 0001588

3rd March, 2016

Ms. Audrey Nafuna Mukhwana,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
03 MAR 2016
APPROVED
P.O. Box 4606-30100 ELDORET

Dear Ms. Mukhwana,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Ethical Implications of Voluntary Informed Consent on a Longitudinal International Health Research in Western Kenya."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1588*** on 3rd March, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 2nd March, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD